

REMARKS

Summary of Advisory Action

Claims 29-50 are pending in this application.

The Examiner maintained the rejections of claims 29-50 as follows:

Claims 29, 31, 33, 34, 45, 47, 49, and 50 stand finally rejected under 35 U.S.C. § 103(a) as being obvious from Forsberg et al. U.S. Patent No. 6,807,797 (hereinafter "Forsberg") in view of Case U.S. Patent No. 4,405,317 (hereinafter "Case").

Claims 37-39, 41, 43, and 44 stand finally rejected under 35 U.S.C. § 103(a) as being obvious from Forsberg and Case in view of Odell et al. U.S. Patent No. 6,263,641 (hereinafter "Odell").

Dependent claims 30, 40, and 46 stand finally rejected under 35 U.S.C. § 103(a) as being obvious from Forsberg/Case/Odell in view of Geprägs U.S. Patent No. 4,781,701 (hereinafter "Geprägs").

And claims 32, 34-36, 42, 45, and 47-50 stand finally rejected under 35 U.S.C. § 103(a) as being obvious from Tanaka et al. U.S. Patent No. 5,716,339 (hereinafter "Tanaka").

Summary of Applicants' Reply

Applicants submit concurrently herewith a Request For Continued Examination under 37 C.F.R. § 1.114.

Applicants have amended claims 29, 39, and 45 to more particularly point out and distinctly claim the subject matter that applicants regard as the invention.

No new matter has been added.

Reconsideration of this application in view of the following remarks is respectfully requested.

Rejections of Claims 29, 31, 33, 34, 45, 47, 49, and 50 Under 35 U.S.C. § 103(a)

Claims 29, 31, 33, 34, 45, 47, 49, and 50 have been rejected under 35 U.S.C. § 103(a) as being obvious from Forsberg in view of Case.

These rejections are respectfully traversed.

Independent Claim 29

Independent claim 29 has been amended to require that the inserted seal structure initially seal the front compartment from the rear compartment. This amendment is supported throughout the specification (*see, e.g.*, paragraph 5, lines 7-9).

Independent claim 29 has also been amended to require that the wet medicament, filled in the rear compartment, contact interior side walls of the chamber. This amendment is plainly apparent from the specification and drawings (*see, e.g.*, FIG. 17C), since there is no other structure or container within the chamber to prevent the wet medicament from contacting interior side walls of the chamber.

The Examiner cited Forsberg, which shows in its FIG. 1 a dual chamber syringe having a barrel 1, neck 2, a piston 3 “inserted to the rear of a bypass 4” (column 17, line 4), a front chamber 5, and a rear chamber 6 (*see* Forsberg FIG. 1).

The Examiner acknowledged that Forsberg “does not teach that the chamber has no interior structures, or the seal having a flow path formable there through.”

The Examiner also cited Case, saying it teaches a seal (34) and barrel (12) having no interior structures.

Note that Case's plunger 34 by itself is not a seal structure that initially seals a front compartment from a rear compartment as required by claim 29. Plunger 34 has a bore 42 and plurality of discharge openings 45 that together extend entirely through the plunger. Thus, plunger 34 by itself cannot seal one compartment from another.

Case discloses that plunger 34 requires inner barrel 16 to be inserted into bore 42 and a plug 50 to be inserted into discharge opening 48 of barrel 16 in order to purportedly function as a seal structure that initially seals a front compartment from a rear compartment.

Case's assembly of parts is not applicants' seal structure.

The Examiner concluded that "[i]t would have been obvious to one of ordinary skill in the art ... to use the seal and barrel structure of Case with the loading method of Forsberg."

The Examiner also said that the "'introduction of the middle piston' step [of Forsberg's method] would simply be replaced with using the piston/breakable seal of Case."

Simply replaced?

This is not a simple substitution of one known element for another.

This is a modification of Forsberg's barrel 1 to remove bypass zone 4 and to substitute a simple element (Forsberg's piston 3) with a complex arrangement of an inner barrel 16 inserted in a plunger 34 and a plug 50 inserted in the inner barrel 16. This involves adding more parts, more cost, and more complexity to Forsberg's syringe.

Why would a person of ordinary skill in the art modify Forsberg's simple piston 3 and bypass zone 4 with Case's more complex assembly of outer barrel 12 (having no interior structures), inner barrel 16, plug 50, and plunger 34?

There is nothing to suggest that Forsberg's device and/or method would be improved by such a modification.

Accordingly, applicants submit that there is no rationale for replacing the simple elements of Forsberg with the complex assembly of Case.

Furthermore, even if Forsberg were combined with Case, that combination would not result in applicants' invention as defined in claim 29. In particular, applicants require filling the rear compartment of the chamber. A method based on the combination of Forsberg and Case would not require the filling of rear chamber 6, but instead the filling of inner barrel 16 which is positioned in rear chamber 6 as a necessary component of the "seal structure."

Applicants also require the wet medicament to contact interior side walls of the chamber. Wet medicament in the combination of Forsberg and Case would contact interior side walls of inner barrel 16, not Forsberg's syringe barrel 1/rear chamber 6.

Applicants further require the rear end of the chamber to be sealed. In the combination of Forsberg and Case, the rear end of inner barrel 16, not syringe barrel 1/rear chamber 6, would be sealed.

In sum, applicants' invention as defined in amended independent claim 29 does not result from the combination of Forsberg and Case, and therefore, claim 29 is not obvious from that combination and should be allowable.

For at least these reasons, dependent claims 31, 33, and 34, which depend either directly or indirectly from independent claim 29, should also be allowable (i.e., dependent claims are allowable if their independent claim is allowable).

Independent Claim 45

Independent claim 45 has also been amended to require that the inserted seal structure initially seal the front compartment from the rear compartment.

Therefore, claim 45 is not obvious from the combination of Forsberg and Case for the same reasons as claim 29 with respect to filling the rear compartment of the chamber, the wet medicament contacting interior side walls of the chamber, and sealing the rear end of the chamber.

Independent claim 45 has further been amended to require that the filling of the front and rear compartments is through open mouth configurations at the respective ends of the chamber. Support for this amendment is found throughout the specification (*see, e.g.*, paragraph 68). Moreover, applicants' specification distinguishes a chamber having an open mouth configuration (*see* FIG. 9) from one that does not (*see* FIG. 3A).

Neither Forsberg nor Case meets these requirements of claim 45. In particular, Forsberg fills front chamber 5 through neck 2 of barrel 1. This top portion of barrel 1 is not an open mouth configuration.

Similarly, both inner barrel 16 and outer barrel 12 of Case have narrowed neck portions ("[t]he inner barrel has reduced neck portion 30" (column 4, lines 40-41) and *see* FIG. 1, outer barrel 12 at cap 22).

Thus, claim 45 is also not obvious from the combination of Forsberg and Case for these reasons and should be allowable.

Similarly, dependent claims 47, 49, and 50, which depend from independent claim 45, should also be allowable (i.e., dependent claims are allowable if their independent claim is allowable).

Accordingly, applicants respectfully request that the rejections of claims 29, 31, 33, 34, 45, 47, 49, and 50 under 35 U.S.C. § 103(a) be withdrawn.

Rejections of Claims 37-39, 41, 43, and 44 Under 35 U.S.C. § 103(a)

Claims 37-39, 41, 43, and 44 have been rejected under 35 U.S.C. § 103(a) as being obvious from Forsberg and Case in view of Odell.

These rejections are respectfully traversed.

For at least the same reasons as discussed above regarding independent claim 29, dependent claims 37 and 38, which depend directly and indirectly from claim 29, respectively, should also be allowable (i.e., dependent claims are allowable if their independent claim is allowable).

And also for at least the same reasons, independent claim 39, which has been amended to require the inserted seal structure to initially seal the front compartment from the rear compartment, and the wet medicament, filled in the rear compartment, to contact interior side walls of the chamber, is also not obvious from the combination of Forsberg and Case.

Odell purportedly discloses methods of manufacturing drug delivery and drug container devices in clean, substantially particular-free areas and, accordingly, does not make up for the deficiencies of Forsberg and Case.

Thus, the combination of Forsberg, Case, and Odell does not render claim 39 obvious and, therefore, claim 39 should be allowable.

For at least these reasons, dependent claims 41, 43, and 44, which depend from independent claim 39, should also be allowable (i.e., dependent claims are allowable if their independent claim is allowable).

Accordingly, applicants respectfully request that the rejections of claims 37-39, 41, 43, and 44 under 35 U.S.C. § 103(a) be withdrawn.

Rejections of Claims 30, 32, 34-36, 40, 42, and 45-50 Under 35 U.S.C. § 103(a)

Claims 30, 40, and 46 have been rejected under 35 U.S.C. § 103(a) as being obvious from Forsberg/Case/Odell in view of Geprägs. And claims 32, 34-36, 42, 45, and 47-50 have been rejected under 35 U.S.C. § 103(a) as being obvious from Tanaka.

These rejections are respectfully traversed.

Geprägs was cited because it purportedly discloses a front syringe barrel with a tapered flow path.

Tanaka was cited because it purportedly discloses a rear chamber filled first with a substance and a front chamber filled next with a dry medication.

Accordingly, neither Geprägs nor Tanaka makes up for the deficiencies of Forsberg and Case as discussed above with respect to amended independent claims 29, 39, and 45.

Therefore, any combination of Forsberg, Case, Odell, Geprägs, and Tanaka does not render obvious independent claims 29, 39, or 45.

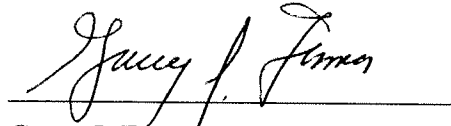
For at least these same reasons, dependent claims 30, 32, 34-36, 40, 42, and 46-50 which depend directly or indirectly from one of claims 29, 39, or 45, should also be allowable (i.e., dependent claims are allowable if their independent claim is allowable).

Accordingly, applicants respectfully request that the rejections of claims 30, 32, 34-36, 40, 42, and 45-50 under 35 U.S.C. § 103(a) be withdrawn.

Conclusion

The foregoing demonstrates that claims 29-50 are allowable. This application is therefore in condition for allowance. Reconsideration and allowance are accordingly respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Garry J. Tuma", is written over a horizontal line.

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